



## **Pulmonx Gets FDA Nod for U.S. Trial of Emphysema Therapy**

*IDE for Study of Zephyr® Endobronchial Valve Approved*

August 27, 2012, Redwood City, CA, USA, Pulmonx, an emerging leader in interventional pulmonology, announced today that the U.S. Food and Drug Administration (FDA) has approved its request for an Investigational Device Exemption (IDE) to commence a multi-center pivotal clinical trial. Pulmonx intends to use the results from this trial to support a subsequent premarket approval application (PMA) for the Zephyr® Endobronchial Valve (EBV). This new trial will incorporate the use of the Pulmonx Chartis® System to plan valve treatment.

The Zephyr® Endobronchial Valve is a minimally invasive device intended to treat patients with emphysema. Emphysema patients suffer from hyperinflation, an increase in volume of the diseased portions of their lungs, which then compresses the healthier areas. The Zephyr® EBV therapy involves bronchoscopic placement of one-way valves designed to reduce volume in the diseased portion of the lungs, thereby improving the ability of the healthier portions of the lungs to function. This is expected to relieve the patient's symptoms, allowing them to increase their activity levels, while promoting better overall health. The brief procedure is relatively easy for physicians to perform, and unlike other presently available Lung Volume Reduction therapies which are irreversible, the Zephyr® implant can later be removed if necessary.

***“We’ve had excellent success with EBV therapy in our practice and with the introduction of the Chartis® System it is rapidly becoming a standard of care here in Europe”***

*“Emphysema is a terribly debilitating disease that affects the lives of literally millions of Americans,”* said Armin Ernst, MD, MHCM, FCCP; Chief, Pulmonary, Critical Care and Sleep Medicine at St. Elizabeth’s Medical Center and Professor of Medicine at Tufts University School of Medicine in Boston, who serves as a co-principal investigator for the Zephyr® trial. *“There is a large, unmet need for non-invasive treatment of emphysema designed for patients who currently have very few options in the U.S.”*

The Chartis® is a first of its kind pulmonary assessment system that provides critical real time information to improve the planning of EBV treatment.

*“A recently published trial in Europe has shown that it is possible to use the new Chartis® technology to plan EBV treatments with a high level of accuracy, which provides the opportunity to obtain with better consistency greater clinical responses in lung function, exercise tolerance, and quality of life measures than was seen in the overall results from the earlier VENT study<sup>1</sup>,”* said Gerard J. Criner, MD, Professor and Chairman Department of Medicine, Chief Division of Pulmonary & Critical Care Medicine, Temple University School of Medicine, also a co-principal investigator for the Zephyr® trial. *“If we can confirm these benefits in this pivotal trial, Pulmonx’s Zephyr® EBV therapy could represent an important breakthrough in the treatment of emphysema in the US.”*

*“We’ve had excellent success with EBV therapy in our practice and with the introduction of the Chartis® System it is rapidly becoming a standard of care here in Europe,”* said Professor Felix

Herth, MD, PhD, FCCP, Chairman and Head of Pneumology and Respiratory Care at Thoraxklinik, University of Heidelberg, who will serve as an advisor for the U.S. study.

The Zephyr® EBV received the CE Mark in 2003. Since becoming commercially available in Europe and select countries worldwide, the company estimates that it has been used to treat approximately 4,000 patients, over 40 percent of whom have been treated in the last 12 months. A recently published multi-center European study reported that, using Chartis®, in those patients who were predicted to respond, there was a statistically significant improvement in target lobe volume reduction and FEV1 at thirty days compared to those who were predicted not to respond. These patients showed a mean percentage increase in FEV1 of 16% (a standard pulmonary function test in which a 15% improvement is commonly considered to be clinically significant) and a mean improvement in quality of life as scored by the SGRQ (St. George's Respiratory Questionnaire, a clinically validated quality of life measure) of 10 points, which is two and one half times the level considered clinically significant.

### **About Pulmonx**

Pulmonx, based in Redwood City, California, and Peseux, Switzerland, is focused on developing and marketing minimally invasive medical devices and technologies for the diagnosis and treatment of pulmonary disorders. [www.pulmonx.com](http://www.pulmonx.com)

The Zephyr® EBV is an investigational device in the United States. Limited by U.S. law to investigational use.

<sup>1</sup>Herth FJ, Eberhardt R, Gompelmann D, Ficker JH, Wagner M, Ek L, Slebos DJ. *Radiological and Clinical Outcomes of Using Chartis® to Plan Endobronchial Valve Treatment*. Published on May 3, 2012 as doi: 10.1183/09031936.00015312 ERJ Express

### Contact

#### Pulmonx

Michael A. Baker, President & CEO

Peseux, Switzerland, Phone: +41 32 557 5800

Redwood City, CA, Phone: +1 (0) 650 216-0150

[mbaker@pulmonx.com](mailto:mbaker@pulmonx.com)

### Source

#### Business Wire

<http://www.businesswire.com/news/home/20120827005896/en>